UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 16, 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: 6(a)(2) Efficacy Review for "Discide Ultra Disinfecting Spray", EPA Reg. No.10492-5; DP Barcode: D285629
Case No. 062029

From: Lorilyn M. Montford LM
Efficacy Review Team
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Through: Emily Mitchell, M.S., Team Leader Emily Mitchell 10/16/02
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To: Sharon Carlisle/Marshall Swindell
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Applicant: Palmero Health Care
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Stratford, CT 06615

Formulation From Label:

Active Ingredient(s)	% by wt.
Isopropyl Alcohol	63.25%
Dimethyl ethyl benzyl ammonium chloride	0.12%
Dimethyl benzyl ammonium chloride	0.12%
Inert Ingredients(s)	36.51%
Total	100.00%

I. BACKGROUND

The applicant has submitted information in accordance with FIFRA Section 6(a)(2), regarding efficacy failure for the product, DisCide Ultra Disinfecting Spray (EPA Reg. No. 10492-0005) against the microorganism *Salmonella choleraesuis*. The last accepted label (dated November 19, 1998?) indicates that the product is a disinfectant for use on hard, non-porous surfaces in hospitals, other medical settings, nursing homes, laboratories and dental suites, when used as directed. The study was conducted by App Tec Laboratory Services located on 2540 Executive Drive, St. Paul, MN 55120.

The data package contained one study (MRID No.457042-01) which included a Statement of No Data Confidentiality Claim, Good Laboratory Practice Statement, and a Quality Assurance Unit Summary.

II. USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces in hospitals, intensive care units, emergency medical settings, central supply, nursing homes, clinics, laboratories, and dental suites. The directions on the last accepted label provide the following information regarding preparation and use of the product: Completely preclean surfaces to be disinfected. DisCide Ultra Disinfecting Spray can be used for this purpose. Then, hold the DisCide bottle approximately 12 inches from the surface and thoroughly wet. Allow to remain for 1 minute. When used as a tuberculocidal disinfectant, allow the surface to remain wet for 5 minutes at 20° C.

The label directions also include special instructions for cleaning and decontaminating against HIV-1 on pre-cleaned environmental surfaces or objects previously soiled with blood/bloody fluids. The label directs the user to: thoroughly wet surface with DisCide Ultra Disinfecting Spray. Allow to air dry. The efficacy of a 1 minute contact time has been shown to be adequate against HIV-1.

III. Comments On The Submitted Efficacy Study

1. MRID 457042-01 "AOAC Germicidal Spray Method".
Study conducted at App Tec Laboratory Services, St. Paul, Minnesota.
Study completion date - June 24, 2002.

This study was conducted against *Salmonella cholerasuis* (ATCC 10708). One lot (Lot No. 14-05152A) of the product was tested using the Germicidal Spray Method as described in the AOAC Methods of Analysis, 15th Ed., 1990. For each exposure period (1 min., 3 min., 5 min.), 60 glass slides (18mm x 36mm) were placed into 60 sterilized glass petri dishes and inoculated with a 48-54 hour old broth of the test organism, with a 5% organic soil load (tryptic soy agar with sheep blood) culture incubated at 35-37°C, at a ratio of 1 carrier per 0.01mL of broth using a calibrated pipettor. The inoculum was uniformly spread over the entire surface of the slide contained in the petri dish. The carriers were dried for 30 minutes at 36°C in 42% relative humidity. Each carrier contained 2 pieces of 9 cm filter paper. Each carrier was sprayed individually at staggered intervals with the product using 2 pumps at a distance of 12

inches each. Each carrier remained in contact with the test substance for one minute, three minutes, or five minutes at room temperature. Following each exposure period, the remaining liquid was drained off of the carrier. Each carrier was transferred to 20mL of Letheen Broth with 0.14% Lecithin and 1.0% Tween 80. The neutralized subcultures were incubated for 44 hours at 36°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included purity, viability, neutralizing subculture medium sterility, carrier sterility, neutralization confirmation, and carrier population.

IV. RESULTS

Table 1. Test Results

MRID Number	Test Organism	Exposure Period	Date Performed	Sample Dilution	Number of Carriers	
					Exposed	Showing Growth
457042-01	*Salmonella choleraesuis*	1 minute[a]	6/12/02	RTU	60	4
		3 minute[b]			60	0
		5 minute[c]			60	0

RTU = Ready to use
a= Inoculation #1 was utilized for the 1 minute exposure period.
b= Inoculation #2 was utilized for the 3 minute exposure period.
c= Inoculation #3 was utilized for the 5 minute exposure period.

Table 2. Carrier Population Control Results

Test Organism	Date Performed	Result
Salmonella choleraesuis (ATCC 10708) - Inoculation #1	6/12/02	9.6 x 10^4 CFU/carrier
Salmonella choleraesuis (ATCC 10708) - Inoculation #2		5.5 x 10^4 CFU/carrier
Salmonella choleraesuis (ATCC 10708) - Inoculation #3		7.7 x 10^4 CFU/carrier

V. Conclusions

Review of the 6(a)(2) data submission confirms that the efficacy data (MRID 457042-01) submitted by the applicant to support use of the product, DisCide ULTRA Disinfecting Spray, as a disinfectant against *Salmonella choleraesuis* does indeed "fail" when tested in the presence of Letheen Broth with 0.14% Lecithin and 1.0% Tween 80 and a 5% organic soil load of sheep blood on hard, non-porous surfaces for a contact time of 1 minute. In three batches of product tested, at least four carriers showed positive growth in the subculture.

Note: *Salmonella choleraesuis,* obtained for two batches of the product, demonstrated efficacy of the product when tested in the presence of Letheen Broth with 0.14% Lecithin and 1.0%

Tween 80 and a 5% organic soil load of sheep blood on hard, non-porous surfaces for a contact time of 3 minutes and 5 minutes.

VI. RECOMMENDATIONS

Review of the 6(a)(2) data submission confirms that the *Salmonella choleraesuis* efficacy data submitted by the applicant do indeed "fail". Our "worst-case" recommendations regarding label changes are to:

- Remove all label claims references to *Salmonella choleraesuis* relative to bacteriocidal efficacy.

- Remove all claims regarding the use of the product as a disinfectant in health care settings (i.e., hospital, intensive care units, emergency medical settings, central supply, nursing homes, clinics, laboratories, and dental suites), as test data indicate that the product is not effective against the nosocomial bacterial pathogen *Salmonella choleraesuis.*